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EXPRESS MAIL LABEL NO.: EV 333487076 US

PATENT

Attorney Docket No. 29191.707.501



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application

PATENT APPLICATION

Inventor(s): Jonathan C. HELLER et al.

Art Unit: 1641

Application No.: 10/760,100

Examiner: Not yet assigned

Filed: January 16, 2004

Title: Assay customization

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - ☒ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; **or**
  - ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
  - C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. ), copies are not enclosed herewith.
  - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).

☐ Attached are the following non-published pending patent applications which may be deemed relevant.

☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.29191.707.501).

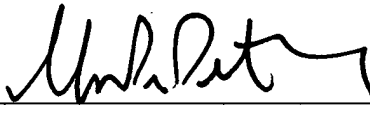
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: \_\_\_\_\_

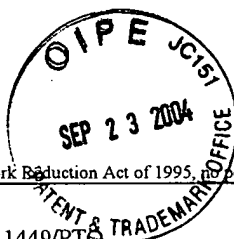
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By: \_\_\_\_\_



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PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
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<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/760,100
				Filing Date	01/16/2004
				First Named Inventor	Jonathan C. HELLER
				Art Unit	1641
				Examiner Name	Not yet assigned
Sheet	1	of	3	Attorney Docket Number 29191.707.501	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-2002/0048777	04/25/2002	Ali et al.	
		US-2002/0127237	09/12/2002	Salceda et al.	
		US-2002/0177140	11/28/2002	Salceda et al.	
		US-2003/0039983	02/27/2003	Sun et al.	
		US-2003/0064377	04/03/2003	Sun et al.	
		US-2003/0078739	04/24/2003	Norton et al.	
		US-2003/0111596	06/19/2003	Becker et al.	
		US-2003/0129760	07/10/2003	Aguilera et al.	
		US-2003/0175707	09/18/2003	Sun et al.	
		US-2003/0194739	10/16/2003	Ali et al.	
		US-2003/0199001	10/23/2003	Pitt et al.	
		US-2004/0053333	03/18/2004	Hitt et al.	
		US-6,593,298	07/15/2003	Jackowski et al.	
		US-6,599,877	07/29/2003	Jackowski et al.	
		US-6,602,855	08/05/2003	Jackowski et al.	
		US-6,617,308	09/09/2003	Jackowski et al.	
		US-6,620,786	09/16/2003	Jackowski et al.	
		US-6,620,787	09/16/2003	Jackowski et al.	
		US-6,627,606	09/30/2003	Jackowski et al.	
		US-6,627,607	09/30/2003	Jackowski et al.	
		US-6,627,608	09/30/2003	Jackowski et al.	
		US-6,677,303	01/13/2004	Jackowski et al.	
		US-6,703,366	03/09/2004	Jackowski et al.	
		US-6,756,476	06/29/2004	Jackowski et al.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Substitute for form 1449/PTO

*(Use as many sheets as necessary)*

Application Number	10/760,100
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Filing Date	01/16/2004
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First Named Inventor	Jonathan C. HELLER
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Art Unit	1641
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Examiner Name	Not yet assigned
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Sheet

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Attorney Docket Number

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**Examiner  
Signature**

Date  
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				Examiner Name	Not yet assigned
Sheet	3	of	3	Attorney Docket Number	29191.707.501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		AURIOLA, Seppo et al., "Enhancement of sample loadings for the analysis of oligosaccharides isolated from <i>Pseudomonas aeruginosa</i> using transient isotachopheresis – electrospray – mass spectrometry". <i>Electrophoresis</i> (1998), 19:2665-2676.	
		FIGEYS, Daniel et al., "High sensitivity analysis of proteins and peptides by capillary electrophoresis-tandem mass spectrometry: recent developments in technology and applications". <i>Electrophoresis</i> , (1998), 19:885-892.	
		GUO, Xu et al., "Analysis of metallonhioneins by means of capillary electrophoresis coupled to electrospray mass spectrometry with sheathless interfacing" <i>Rapid Commun. Mass Spectrom.</i> (1999), 13:500-507.	
		KAISER, Thorsten et al., "Capillary electrophoresis coupled to mass spectrometer for automated and robust polypeptide determination in body fluids for clinical use". <i>Electrophoresis</i> (2004), 25:2044-2055.	
		KAISER, Thorsten et al., "Capillary electrophoresis coupled to mass spectrometry to establish polypeptide patterns in dialysis fluids". <i>Journal of Chromatography A</i> (2003), 1013:157-171.	
		NEUSUB, Christian et al., "A robust approach for the analysis of peptides in the low femtomole range by capillary electrophoresis-tandem mass spectrometry". <i>Electrophoresis</i> (2002), 23:3149-3159.	
		PARONI, Rita et al., "Creatinine determination in serum by capillary electrophoresis". <i>Electrophoresis</i> (2004), 25:463-468.	
		RHODE, E. et al., "Comparison of protein mixtures in aqueous humor by membrane preconcentration – capillary electrophoresis – mass spectrometry". <i>Electrophoresis</i> (1998), 19:2361-2370.	
		STROINK, Thom et al., "On-line coupling of size exclusion and capillary zone electrophoresis via a reversed-phase C18 trapping column for the analysis of structurally related enkephalines in cerebrospinal fluid". <i>Electrophoresis</i> (2003), 24:897-903.	
		WITTKKE, Stefan et al., "Determination of peptides and proteins in human urine with capillary electrophoresis-mass spectrometry, a suitable tool for the establishment of new diagnostic markers". <i>Journal of Chromatography A</i> (2003), 1013:173-181.	

Examiner signature		Date Considered	
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